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ANESTHESIA SAFETY: FILTER NEEDLE USE WITH GLASS AMPULES

by

debran L. Harmon

A project submitted to the School of Nursing

in partial fulfillment of the requirements for the degree of

Doctor of Nursing Practice

UNIVERSITY OF NORTH FLORIDA

BROOKS COLLEGE OF HEALTH

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Unpublished work c. debran Lynn Harmon

Certificate of Approval

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Dedication & Acknowledgements

This work is dedicated to the collaborative anesthesia care teams that continuously work to improve patient safety, person-centered care, and better patient outcomes by providing quality services founded in the best evidence-based practice.

I would like to acknowledge all of the professional mentors that have shared their time, wisdom, advice, and expertise in order to make this project possible. Thank you from the bottom of my heart. I would also like to gratefully thank my spouse, family, friends, and students that have provided the inspiration and motivation to pursue a terminal advanced clinical practice doctoral degree. Through this journey, I have been humbly reminded that "all things are possible for the person who believes," The Bible, Mark 9:23.

Table of Contents

List of Tables

Abstract

Glass particle contamination of medication occurs when opening ampules which may cause patient harm. The use of filter needles reduces this risk. Many anesthesia providers use ampules daily, but do not use filter needles when aspirating medications from ampules. In addition, filter needles may not be readily available at the anesthesia medication preparation site. Not using filter needles or having them available for use can increase the risk of patient harm by glass particle contamination. The purpose of this project was to increase anesthesia provider's knowledge thereby improving compliance with evidence-based standards when preparing medications from ampules. The goal is to increase filter needle use when medication is aspirated from an ampule in order to decrease the risk of glass particle contamination to the patient. This project consisted of a one-group pre/post intervention design using a piloted self-developed survey, an education intervention, and tracking of filter needle use. The convenience sample of eighty-three recruited anesthesia providers included anesthesiologists, nurse anesthetists, and anesthesiologist assistants that consented to participate. The filter needle inventory was tracked via an existing software program to determine filter needle use three months prior and three months after the intervention. Data were collected and analyzed using descriptive statistics. The results of this project found greater awareness among participants of standards and organizations regarding filter needle use with ampules, greater awareness of availability of filter needles on anesthesia carts, and a five-fold increase in filter needle usage by participants three months following the intervention as compared to three months prior to the intervention.

Keywords: filter needle, glass particle contamination, anesthesia, patient safety, and safe injection practices

Chapter One: Introduction

Healthcare professionals are educated to be advocates for patient safety. Part of this advocacy involves preparing and administering medications safely. This is especially true for anesthesia providers preparing medications from glass ampules for injection into patients receiving anesthesia services. Glass particle contaminations (GPC) from ampules and associated harmful effects have been known for more than sixty years. Filter needles can be used to minimize this risk, yet many anesthesia providers do not routinely use filter needles when aspirating medication from glass ampules. Nurse anesthetists have an ethical responsibility to the patient to protect them from harm and be an advocate for their welfare (AANA, 2010). Following established medication preparation standards, known as safe injection practices, regarding the use of filter needles with ampules is a responsibility of all anesthesia providers to promote patient safety and improve patient outcomes.

The standards of care regarding the preparation of medications from glass ampules are provided by the American Society of Hospital-System Pharmacists (ASHP) and the Infusion Nurses Society (INS). Anesthesia personnel should be aware of and practice within the scope of these standards when providing anesthesia services. This project will use research to re-educate anesthesia providers on the best evidence-based practice when preparing medication from glass ampules. The focus of this project is for anesthesia providers to follow current established standards by using a filter needle each and every time a medication is aspirated from a glass

ampule. This practice reduces the risk of glass particle contamination and potential harm to patients when administering medications from ampules.

Background

Anesthesia professionals are taught early in their educational experience the proper techniques of preparing and administering medications based on established standards founded in the best evidence. This includes the preparation of medication from glass ampules. However, many anesthesia providers do not continue to practice these techniques once in clinical practice. A survey distributed in the Fall of 2011 at a southeastern nurse anesthesia conference, indicated that 85% (105/124) of the nurse anesthesia participants (*n*=124) use glass ampules daily or weekly and that 61% (76/124) of those questioned rarely or never used filter needles when aspirating medications from glass ampules (Farmer, Harmon, Monaghan, & Pabalate, 2012). This data indicates a need to re-educate members of the anesthesia community on the existing standards regarding the use of filter needles when preparing medications from glass ampules.

Standards

Two professions in healthcare have been concerned about glass particle contamination of medications prepared from glass ampules, pharmacy and nursing. The United States Pharmacopeia (USP) has established standards for how medications should be safely prepared from a glass ampule (USP, 2008). In the 1980s, the Food & Drug Administration delegated the problem of contamination of sterile medication preparations to the USP to provide guidelines for safe preparation and administration of medications. The pharmacy standard is found in the USP Chapter 797 titled, Pharmaceutical Compounding: Sterile Preparations (2008). The American Society of Hospital-System Pharmacists endorsed this standard in the clinical setting as a

guideline when preparing medications from glass ampules in hospital pharmacies (ASHP, 2008). It is interesting to note that the accrediting body of healthcare organizations, The Joint Commission, also considers USP 797 as "best practice," (Kastango, 2007).

The Infusion Nurses Society additionally has developed standards for nurses when preparing medications from ampules. The nursing standard of practice regarding this issue states, "A blunted filter needle or filter straw shall be used when drawing medication from glass ampules" (INS, 2011, p. S34). This standard is in agreement with both the USP and ASHP, and should be practiced by all clinicians preparing medications from glass ampules, including the anesthesia community (anesthesiologists, certified registered nurse anesthetists, and anesthesiologist assistants). This standard goes one step further by suggesting the use of a blunt tip filter needle, instead of a sharp tip filter needle, to reduce the risk of occupational injury.

The American Association of Nurse Anesthetists (AANA) does have a position statement 2.13 (PS 2.13) regarding *Safe Practices for Needle and Syringe Use* (2012) which discusses safe injections practices. This position statement emphasizes infection control concerns from microbial contamination which is extremely important in protecting patients. From this PS 2.13, the AANA developed *Safe Injection Guidelines for Needle and Syringe Use* (2014). However, this position statement and these guidelines do not address the risk for harm from glass particle contamination when using ampules. The evidence clearly shows that the risk of patient harm can occur from glass particle contamination. The AANA needs to update this position statement and guidelines to include safe medication preparation by using a filter needle when aspirating medications from ampules.

Abbreviated Literature Review

1. Glass contamination occurs when opening glass ampules:

   The issue of glass particle contamination in parenterally administered medication upon opening of single-dose glass ampules is supported in the literature (Preston & Hegadoren, 2004; Zabir, Choy, & Rushdan, 2008; and Kalinski et al., 2012).

2. Patient's can be harmed from glass particle contamination:

   Glass particle contamination may cause harm to patients by causing pain at the injection site, infusion phlebitis, pulmonary thrombi and micro-emboli, end-organ inflammation (kidney, liver, spleen, and lungs), granuloma formation, and modulating inflammatory effects (Brewer & Dunning, 1947; Shaw & Lyall, 1985; Puntis, Wilkins, Ball, Rushton, & Booth, 1992; Heiss-Harris & Verklan, 2005; Jack et al., 2010).

3. Filter needle use reduces the amount of glass particle contamination (Preston & Hegadoren, 2004; Sabon, Cheng, Stommel, & Hennen; 1989; Kalinski et al., 2012).

4. USP/ASHP/INS standards are established to minimize patient exposure to glass particle contamination and reduce risk of injury:

   - USP Chapter <797> Pharmaceutical Compounding: Sterile Preparations (2008)
   - ASHP Practice Basics-Chapter 16: Aseptic Technique, Sterile Compounding, and IV Admixture Programs (2008)
   - INS Standards of Practice 2011- Standard 28.6

5. Anesthesia professionals routinely do not follow established guidelines for proper medication preparation with glass ampules (Hemingway, Malhotra, Almeida, Azadian, & Yentis, 2007; Farmer et al., 2012).

Problem

The Farmer et al. (2012) study rendered three conclusions. Medications from glass ampules are frequently given by anesthesia professionals. Anesthesia providers are not using intravenous (IV) filter needles when aspirating medications from glass ampules. Most anesthesia providers are not aware of a protocol/policy/standard regarding IV filter needle use with ampules.

Project Purpose

The purpose of this project is to reduce glass particle contamination when anesthesia providers prepare medications from ampules by using 5-micron filter needle. The objective of the project is to improve anesthesia provider compliance with existing standards regarding filter needle use when preparing medications from glass ampules. An educational intervention was presented that informed participants of the research supporting existing standards regarding filter needle use with ampules. Anesthesia carts were stocked with filter needles for use at the medication preparation site for ready availability. Finally, participants were taught how to minimize the risk of patient harm from GPC founded in best evidence-based practice by following existing standards. Filter needle use was tracked to determine usage before and after the educational intervention.

Definition of Terms

Anesthesia providers (AP): anesthesiologists certified registered nurse anesthetists, and anesthesiologist assistants.

Filter needle/Straw: Filter Needle- hypodermic (sharp) needle, 19 gauge (g), 1.5 inch, with a 5 micron filter (used to filter out very fine glass particles); Blunt Filter Needle- 18g, 1.5 inch, with a 5 micron filter; Filter Straw- flexible straw for medication aspiration from ampules, 1.75 inch, with a 5 micron filter.

Glass particle contamination: tiny (5-100 microns) glass particles found in medication that has been aspirated from a glass ampule.

Educational intervention: a series of events to educate participants on the research that supports filter needle use with glass ampules. The intervention included a brief PowerPoint slide educational presentation at the completion of the initial survey regarding filter needle use. Filter needles were placed in anesthesia providers narcotic bags by the operating room pharmacist during morning narcotic distribution and filter needles were made available (stocked) at the medication prep site on the anesthesia cart. Usage was tracked. A reminder to use filter needles with ampules was sent via an evening email operating room assignment. A pager reminder following the first week of the campaign was sent to all APs. An ASHP (2008) poster was placed near the anesthesia cart and posted in OR pharmacy explaining proper technique when aspirating medication from an ampule using a filter needle.

Qualtrics. A software survey tool (version 58147, 2014, Provo, Utah) used to make, distribute, generate, and analyze data from self-developed surveys.

Chapter Two: Review of the Evidence

Chapter two is a review of the literature that considers the best evidence to use in order to implement a change in clinical practice. The review includes the synthesis of evidence related to the potential for patient harm from glass particle contamination when preparing and administering medications from ampules. Evidence is also discussed regarding the use of filter needles to decrease the risk of glass particle contamination, the existing pharmacy and nursing standards on the topic, and the clinical practices of anesthesia providers when preparing medications from glass ampules. This chapter begins with an explanation of the search strategy used to collect the evidence, presents the body of evidence as well as the strength of the evidence, and ends with a discussion of the implications for practice based on the evidence.

Search Strategy

The PICOT principle was applied to the search strategy for this work. That is, "P" for population/clinical problem, "I" for intervention, "C" for comparator/control, "O" for outcome, and "T" for time frame (Glasziou, Del Mar, & Salisbury, 2007). The PICOT statement used in this search strategy is: Do anesthesia providers (P), after participating in an educational intervention (I, C), use filter needles when preparing medications from ampules (O) by following established standards three months (T) after an educational intervention? The search limited to studies in the English language, those that used a variety of medication routes with ampules (i.e., intravenous, intramuscular, and neuroaxial), and studies that directly related to the PICOT statement. No time limitation was used in order to find early seminal studies. Excluded studies

were those not translated into the English language, work that emphasized only the occupational hazards of opening glass ampules, and those studies that focused on particle contamination from medications other than glass (e.g., rubber, plastic, metal, paint chips).

The following electronic databases were used to accrue evidence on the topic of glass particle contamination, filter needle use with ampules, and patient safety: EBSCOhost, CINAHL, PubMed, Medline, Ovid Journals, and Cochrane Libraries. Key word searches included the terms: filter needle, glass particle contamination, ampule, anesthesia, patient safety, and safe injection practices. A combination of the search terms was then used to narrow the focus of evidence that related most closely to the PICOT statement. Finally, a manual search was conducted using the reference lists in the studies selected from the electronic database search to find relevant studies.

Forty-two studies were found that related to glass particle contamination and filter needle use with ampules using the inclusion criteria from the electronic databases. Fourteen articles were selected that related closely to the PICOT statement. The level of evidence was determined using the "Hierarchy of evidence for intervention studies" by Melnyk & Fineout-Overholt (2011). This hierarchy consists of seven levels of evidence (listed from highest to lowest):

1. Level I (highest): Systematic review or meta-analysis
2. Level II: Randomized controlled trial (RCT)
3. Level III: Controlled trial without randomization
4. Level IV: Case-control or cohort study
5. Level V: Systematic review of qualitative or descriptive study
6. Level VI: Qualitative of descriptive study

7. Level VII (lowest): Expert opinion or consensus

Fourteen studies were selected that related to glass particle contamination, patient harm, and filter needle use consisted of (in order by level): one systematic review of eleven random controlled trials, five randomized controlled trials, two controlled trials, two cohort studies, one case study, one expert opinion article, and two recent studies that were presented in 2012 at a national anesthesia nursing organization annual conference meeting which included one bench study and one descriptive survey study (Appendix F). Lower levels of evidence were used in this literature review if they related directly to the PICOT question.

The Research

Glass particles

Glass particle contamination has been known to occur upon opening glass ampules for many years. Carbone-Traber & Shanks (1986) found that glass particle contamination does occur when opening ampules and smaller ampules had fewer particles than larger ampules (1< 5< 20 milliliter (mL)). Zabir et al. (2008) added to this knowledge by demonstrating that the size and type of needle used to aspirate the contents of an ampule mattered in reducing glass particle contamination. They found that an 18 gauge (g) filter straw (FS) had less glass particle contamination than larger bore hypodermic needle (18g FS< 23g< 18g) and confirmed the earlier work by Carbon-Traber & Shanks that larger ampules have greater particle contamination.

The technique used to measure and count glass particles after ampule opening in earlier studies was limited in accuracy by the level of experience of the researcher using the microscope and the type of microscope used during the microscopic particle count test. This technique uses a microscope to view glass particles at a magnification power of 10X or 60X using objectives

with a light source either above or below the visual field. The microscope either has an ocular grid in the lens or a grid on the slide or cover slip to measure the glass particles. Glass particles are often difficult to see because many are transparent, as opposed to amber colored. Counting accurately depends upon the ability of the microscopist. An innovative technique was developed using new technology (**FlowCAM**®) to count and measure glass particles more accurately and consistently (Brown, 2010). The new technology uses a digital imaging analyzer/flow cytometer equipped with a 10x electronic microscope and a 100um flow cell. This method was used in a recent study comparing glass particle contamination when aspirating medication from an ampule using either a filtered or a non-filtered needle (Kalinski et al., 2012). This study confirmed that glass particle contamination does occur when opening ampules and using filter needles reduces the amount of glass particle contamination.

Patient harm

Glass particle contamination (GPC) has been known to cause pathology for decades. Brewer & Dunning (1947) studied the effect of GPC on animals and found that large doses of glass particles caused end organ (liver, lungs, kidneys, spleen, and intestines) damage and pulmonary vascular obstruction (thrombi/emboli). Garvan & Gunner (1964) confirmed the above findings and added that GPC caused inflammatory reactions and granuloma formation in the liver, lungs, kidneys, spleen, and intestines. These studies are the early foundation for the indication that GPC may cause patient harm. More recent work by Puntis et al. (1992) found that glass particles were located in the lungs of neonates postmortem after receiving intravenous nutrition (prepared from glass ampules) compared to infants that died from sudden infant death syndrome that had no glass particles found in the lungs; glass particles caused pulmonary granulomas and hypertension in 5% of the 41 infants examined postmortem. Jack et al. (2010)

found that GPC occurs even with filtration when used in the pediatric intensive care unit and that there was a suppression of the immune system, measured by decreased cytokine activity, when the effects of glass particles were examined in vitro on human umbilical vein endothelial cell and murine macrophages. A systematic review of eleven RCTs considering if in-line filters should be used in peripheral catheters to prevent infusion phlebitis concluded that no recommendation to use the in-line filters could be made because of the unexplained variation between trails that existed. However, the researchers discovered that in all eleven RCTs, the use of in-line filters reduced infusion phlebitis (Niel-Weiss, Stijnen, & van den Broek, 2010).

Filter needle use

The use of filter needles or filter straws has been shown to reduce the amount of GPC. Sabon et al. (1989) found that using filter needles decreased the risk of injecting glass particles into a patient and recommend using filtration when drawing medications from single-dose ampules. Preston & Hegadoren (2004) support the use of filter needles to reduce GPC and emphasize that filter needles should be used when preparing medication from ampules for intramuscular injections to protect the patient. Hemingway et al. (2007) recommended the use of a filter straw when drawing medications from ampules when used for regional anesthesia. In a more recent study, Kalinski et al. (2012) found that using a filtered needle reduced GPC by 85%. Thus, using a filtered needle decreases the risk of patient harm by exposing the patient to fewer glass particles. The cost of filter needles purchased from medical supply company's average about $32.00 per box of 100 compared to the cost of blunt needles which cost approximately $13.00 per box of 100. This is a relatively inexpensive way to reduce glass particle contamination and decrease patient risk for potential harm.

Anesthesia practice

Many AP use ampules daily in practice, but do not use filter needles when preparing medications. A survey (Farmer et al., 2012), presented at a southeastern nurse anesthesia conference, found that 85% of anesthesia providers (AP) use ampules frequently in practice, 61% do not routinely use filter needles, 69% indicated that filter needles were not readily available at the anesthesia medication preparation site, and 86% of AP were not aware of a policy or protocol regarding filter needle use with glass ampules (*n= 124*). This indicates a need to educate AP regarding filter needle use with ampules, make filter needles available at the anesthesia medication preparation site, and a call for an improvement in awareness of research based standards for filter needle use with ampules among AP.

Filter needle standards

Standards regarding filter needle use have been developed by pharmacy and nursing organizations to promote patient safety, reduce potential harm, and improve patient outcomes with relatively low cost to the institution. The USP, ASHP, and INS have very specific standards for AP to follow when preparing medications from ampules. The USP chapter 797 titled *Pharmaceutical Compounding: Sterile Preparations* (2008) was designed to develop pharmacy standards for patient safety and prevent patient harm. USP 797 standard requires use of a filter needle when preparing medication from an ampule and use of an alcohol swab to clean the neck of the ampule before breaking it open (2008). The ASHP 2008 guidelines involve the above USP 797 standard and the use of a 5-µm filter needle or straw when drawing medication from a glass ampule. The INS (2011) Standard 28.6 states: "a blunted filter needle or filter straw shall be used when drawing medication from glass ampules" (p. S34).

Practice Implications Based on the Evidence

The review of literature strongly suggests that glass particle contamination of medication occurs when opening an ampule, filter needle use reduces glass particle contamination, and GPC may harm patients. Anesthesia providers do not routinely use filter needles when preparing medications from ampules, are not aware of established filter needle use standards or organizations that endorse these standards, and AP may not have filter needles readily available on the anesthesia cart where medications are prepared (Farmer et al., 2012). The purpose of this project was to educate anesthesia providers about the research regarding filter needle use with glass ampules to reduce GPC by having them participate in an educational intervention. They were provided information on the evidence for filter needle use with ampules as well as content about the organizations that endorse these standards. Filter needles were stocked on the anesthesia cart for ready availability where AP regularly prepares medications from ampules at the participating facility. The goal of this project was to improve patient safety by reducing GPC by AP compliance to evidence-based practice standards when preparing medications properly by using a filter needle with ampules.

Summary

Chapter two includes a synthesis of the best evidence to support the use of filter needles by APs when preparing medications from ampules to reduce GPC. Use of filter needles is consistent with recognized best practice standards on filter needle use with ampules developed by the USP, ASHP, and INS. The Joint Commission, accrediting body of healthcare organizations, considers USP standards/guidelines as best practice (Kastango, 2007). By using filter needles with ampules and following established standards, anesthesia providers can

maximize patient safety and improve patient outcomes with minimal financial impact to the organization (e.g., extended hospital stay for IV antibiotic therapy for phlebitis).

Chapter Three: Methods for Implementation

Chapter three presents the methodology used in this project. The sections included in this chapter are: project design; sample and setting; methods- intervention, outcomes, and timeline of project; protection of human subjects; feasibility; and statistical analysis. A piloted pre and post intervention survey was developed to determine filter needle use with ampules among anesthesia providers. An educational campaign intervention was implemented with the purpose of effecting change in anesthesia practice regarding filter needle use with ampules

Design

The project used a one-group pre and post test design using a nine question piloted self-developed survey via a link emailed before and after an educational campaign to the participants. Inventory of filter needle use was tracked via the hospital inventory tracking software. These data were retrieved by a senior supply system analyst employed by the institution. A descriptive analysis of the pre and post survey results were analyzed via the Qualtrics (2014) survey analysis tool. Inventory of filter needle use in the operating room by the anesthesia providers were tracked pre and post education intervention and compared.

Sample and Setting

An invitation to participate in this project was sent by email via the Qualtrics (2014) distribution tool to 83 anesthesia providers (sample). Data were collected from 83 anesthesia professionals that gave consent to participate in the pre/post education intervention survey. The

convenience sample of participants consisted of 35 anesthesiologists, 42 certified registered nurse anesthetists, and 6 anesthesiologist assistants. The filter needle inventory data was collected from the anesthesia department records of the purchase history inventory software system in a not-for-profit, 528-bed tertiary full service hospital in northeast Florida (setting). The purchase history inventory data were collected by a senior system supply analyst.

Methods

Intervention

The education intervention consisted of the following components:

1. Pre/post nine question self-developed survey deployed via Qualtrics (2014) survey tool (Appendix D).
2. Educational campaign
    a. Fourteen slides PowerPoint education presentation regarding the research foundation of filter needle use with ampules based upon established standards given at the end of the initial survey via electronic link (Appendix E).
    b. Placement of filter needles in the anesthesia provider's narcotic bag when checked out from pharmacy.
    c. Email reminder to use filter needles sent to all providers via the anesthesia assignment sent the evening prior to the day of assignment.
    d. One time pager reminder to use filter needles with ampules during the study period.

e. Placement of a poster near each anesthesia cart and in posted on the OR pharmacy door regarding proper technique using filter needles with ampules (Appendix C).
f. Informal discussion regarding filter needle use with ampules with anesthesia providers by author as opportunities presented them during the course of the working day.

Outcomes

The outcomes of interest include:

1. Anesthesia provider change in practice by using filter needles when preparing medication from ampules per existing standards of practice.
2. Increased awareness of the evidence supporting the established standards and organizations that endorse these standards regarding filter needle use with ampules.
3. Ready availability of filter needles for use at the anesthesia medication preparation site on the anesthesia cart.
4. Reduced GPC by anesthesia providers from using a 5 micron filter needle when preparing medications from glass ampules.

Project Timeline

Phase I: Fall Term 2012- writing chapters 1: Introduction & 2: Review of the Evidence

Phase II: Spring Term 2013- writing chapter 3: Methods for Implementation; re-write chapters 1-3 with DNP Committee suggested edits

Phase III: Summer Term 2013- DNP Committee approval of chapters 1-3, initial preparation of Institutional Review Board (IRB) applications for participating hospital and the University of North Florida (UNF)

Phases IV: Fall Term 2013- survey pilot test, education intervention development, monthly inventory count- meeting with hospital senior system supply analyst, and statistical analysis via Qualtrics- meeting with Center for Instruction and Research Technology professionals at UNF

Phase V: Fall Term 2013- IRB Applications completed

Phase VI: Spring Term 2014- submission of two IRB applications; after IRB approval from both institutions, initiation of project

Summer Term 2014- Project Implementation

Fall Term 2014- Complete write up; Project Presentation; Dissemination of Results to stakeholders and participants; graduation- December 2014

Protection of Human Subjects

Approval of the project was granted for exempt review by the IRB from participating the institution and the university (Appendices A/B). Permission to use the provider email list from the anesthesia department was granted by the president of the participating anesthesia group. Electronic informed consent was obtained by the participants prior to the pre/post education intervention surveys (Appendix D). Permission to use data found in the filter needle inventory tracking system at participating institution was obtained via IRB approval.

Feasibility

This project was cost effective and the resources were readily available for implementation. The self-developed survey was created in the survey software Qualtrics (2014) which was free to the author as a faculty member at the university. Microsoft Office PowerPoint 2007 was used for creating the 14 slide presentation education intervention (Appendix E). This

presentation was added as an electronic link at the end of the initial Qualtrics (2014) survey. The filter needle tracking software was already in use at the hospital, no additional cost was incurred. A senior system supply analyst retrieved the purchase history inventory data from the tracking software. Filter needles were already present and regularly stocked in the anesthesia cart where medications from ampules are prepared. The operating room pharmacist placed filter needles in the narcotic bags when filling provider narcotic morning requests and posted the filter needle use with ampule poster on the operating room pharmacy door. The participants in this project had access to a computer to participate in the surveys and PowerPoint education presentation.

Statistical Analysis

Descriptive statistics (percentages) were generated using the Qualtrics (2014) software survey tool to compare pre and post intervention survey data. Monthly filter needle inventory in the form of purchase order history were compared and analyzed: three months pre-intervention and tracked for three months post education intervention. Chapter four discusses the statistical data results.

Summary

This chapter discussed the methodology for project implementation, outcomes of interest, project timeline, plan for protection of human subjects, feasibility of the project, and the plan for statistical analysis for the data collected from the project. The overall objective of the project to improve anesthesia provider compliance, based upon the research, with existing standards when preparing medications from glass ampules were met when the amount of filter needle usage increased in the months following the education intervention. Accomplishing this objective was determined by evaluating participant responses on the pre/post intervention survey compared to

the data collected from the tracking of filter needle use via the purchase order history. This data will be presented in the next chapter, Chapter 4: Results.

Chapter Four: Results

Chapter four presents descriptive statistical analysis of the data collected from this project. The results are subdivided into two sections: pre-intervention and post-intervention survey data and filter needle inventory of purchase order history data. The chapter concludes with a discussion of unintended consequences of the implementation project, both positive and negative. These results are written with the overall project objective in mind: to improve anesthesia provider compliance with evidence-based standards when preparing medications from glass ampules by using filter needles.

A link to an electronic survey was emailed to eight-three anesthesia providers on April 1, 2014, with permission to use emails from the president of the participating anesthesia group, via Qualtrics (2014) survey distribution tool. The group consisted of 35 Anesthesiologists, 42 Certified Registered Nurse Anesthetists (CRNAs) and six Anesthesiologist Assistants (AAs) during the time period of the project. The responses were collected and analyzed anonymously via Qualtrics (2014) in aggregate form. All percentages were rounded off to the nearest whole number.

Pre/Post-Intervention Survey Data

The initial survey was open for the entire month of April 2014. The response rate of the initial survey was 52 %; 43 providers out of 83 participated in the survey. Of the 43 participants, 13 were Anesthesiologists (30%), 24 were CRNAs (56%), and five were AAs (11%); mean (14),

range (19). One participant did not answer the first question on the survey identifying type of provider (*n*=42). The largest provider group in the initial survey consisted of CRNAs (56%; 24/43).

The follow-up survey was open the entire month of July 2014. An electronic link to this survey was sent to the same 83 anesthesia providers as the initial survey via email, post-education intervention (Table 1). The response rate was 41% with 34 participants including: eight Anesthesiologists (24%), 23 CRNAs (68%), and three AAs (9%); mean (11), range (20). Eighty-five percent (29/34) of the participants indicated that they participated in the initial survey and 15% (5/34) did not take the initial survey. Again, similar to the first survey, most of the participants in the follow-up survey were CRNAs (68%). Table 1 compares the type of anesthesia provider of the pre/post-intervention surveys.

Table 1

Comparison of Type of Provider in Pre/Post Intervention Surveys

Survey*/Provider:	A	CRNA	AA	Mean	Range
1 (*n*= 42) percentage	30	56	11	33	45
(*n*= 42) number	13	24	5	14	19
2 (*n*= 34) percentage	24	68	9	33	59
(*n*= 34) number	8	23	3	11	20

*Note. Survey 1= pre-intervention survey results; Survey 2= post-intervention survey results; Table 1 (n=42). All other responses (*n*= 43); A= anesthesiologist; CRNA= certified registered nurse anesthetist; AA= anesthesiologist assistant

Years in Practice

Of the 43 participants who completed the initial survey, 28% have been practicing anesthesia for 1-2 years, 30% 3-5 years, 21% 6-10 years, 0% 11-15 years, 2% 16-20 years, and

19% twenty or more years. The initial survey indicated that fifty-eight percent (25/43) of the participants had less than six years of anesthesia practice. The majority of participants were relatively new to the profession compared to the 21% (9/43) of providers that had 16 to greater than 20 years of experience.

Of the 34 participants who completed the follow-up survey, 44% had been practicing anesthesia for 1-2 years and 48% had been in practice for 3-10 years. Zero percent of the participants had 11-15 years of experience. Only 3% of the participants had 16-20 years of experience and 6% had greater than 20 years of experience. These data are similar to the first survey participants in that most of them had less than 11 years of experience in anesthesia practice. Table 2 compares the years of anesthesia practice of the initial and follow-up survey.

Table 2

Comparison of Years of Anesthesia Practice

Survey/Years:	1-2	3-5	6-10	11-15	16-19	>20	Mean	Range
1 (*n*= 43) percentage	28	30	21	0	2	19	17	28
(*n*= 43) number	12	13	9	0	1	8	7	12
2 (*n*= 34) percentage	44	24	24	0	3	6	17	41
(*n*= 34) number	15	8	8	0	11	2	6	13

Ampule and Filter Needle Use and Availability

In the pre-intervention survey, ninety-one percent (39/43) of the participants indicated that they used 1-15 medication ampules per day, but only 16% (7/43) used filter needles all the time when preparing medications from ampules, and 40% (17/43) said that filter needles were not readily available at the medication preparation site on the anesthesia cart. These data correlate with the findings from the Farmer et al. (2012) study that reported 85% of participants

(*n*=124) used ampules daily or weekly, 61% rarely or never used filter needles, and 50% of the participants stated that filter needles were not readily available (Tables 3, 4, and 5).

The post-intervention survey results indicated that ninety-one percent of the participants used 1-15 glass ampules a day when preparing medications. Of these, 27% rarely or never used filter needles with ampules and 39% used filter needles all the time or often when preparing medications from ampules. Sixty-five percent of the participants indicated that filter needle were readily available at the medication preparation site compared to 24% that answered no filter needles were not available. Twelve percent indicated "unknown" if filter needles were readily available (Tables 3, 4, and 5). Table 3 depicts data of ampule use per day by anesthesia providers. Table 4 lists data of anesthesia provider filter needle use. Table 5 indicates the availability of filter needles at the anesthesia medication preparation site.

Table 3

Anesthesia Provider Ampule Use per Day

Survey/Amp Use:	0	1-5	6-10	11-15	16-19	>20	Mean	Range
1 (*n*= 43) percentage	2	30	33	28	2	5	17	31
(*n*= 43) number	1	13	14	12	1	2	7	13
2 (*n*= 34) percentage	3	32	44	15	6	0	17	41
(*n*= 34) number	1	11	15	5	2	0	6	14

Table 4

Filter Needle Use by Anesthesia Providers

Survey/FN Use:	Often/All the time	Sometimes	Rarely/Never	Mean	Range
1 (*n*= 43) percentage	32	28	40	33	12
(*n*= 43) number	14	12	17	14	5
2 (*n*= 34) percentage	39	35	27	33	12
(*n*= 34) number	13	12	9	11	4

Table 5

Availability of Filter Needles for Anesthesia Providers

Survey/FN Availability:	Yes	No	Unknown	Mean	Range
1 (*n*= 43) percentage	51	40	9	33	42
(*n*=43) number	22	17	4	14	18
2 (*n*= 34) percentage	65	24	12	33	53
(*n*= 34) number	22	8	4	11	18

Facility Filter Needle Use Policies/Standards or Agencies/Organizations with Standards

Seventy-two percent (31/43) of participants in the initial survey indicated that they were not aware of any policy or standard at their facility regarding filter needle use with glass ampules. When asked if they were aware of any agencies or organizations that had standards regarding filter needle use with ampules, 65% (28/43) answered unknown, signifying they were not aware of any agencies or organizations that had existing standards (Tables 6 and 7). These data are also consistent with data collected in the 2012 Farmer et al. Eighty-six percent of the participants (*n*=124) in that study claimed not to be aware of any policy or protocol that required filter needle use with ampules.

Of the participants in the follow-up survey, 53% were not aware of a facility standard regarding filter needle use with ampules, while 35% said “yes” they were aware of a facility standard. Twelve percent indicated it was “unknown” if their facility had any standards regarding filter needle use with ampules. When asked about any agencies or organizations with standards for filter needle use with ampules, 41% indicated “yes” they knew of agencies or organization with standards, 9% said “no”, and 50% said “unknown” (Tables 6 and 7). Table 6 depicts awareness of the anesthesia provider of facility standard regarding filter needle use with glass

ampules. Table 7 represents awareness of anesthesia provider of any organizations that have existing standards regarding filter needle use.

Table 6

Facility Standards Regarding Filter Needle Use

Survey/ Facility Standard:	Yes	No	Unknown	Mean	Range
1 (*n*= 43) percentage	14	72	14	33	58
(*n*= 43) number	6	31	6	14	25
2 (*n*= 34) percentage	35	53	12	33	41
(*n*= 34) number	12	18	4	11	14

Table 7

Organizations with Filter Needle Use Standards

Survey/ Agency Standard:	Yes	No	Unknown	Mean	Range
1 (*n*= 43) percentage	28	7	65	33	58
(*n*= 43) number	12	3	28	14	25
2 (*n*= 34) percentage	41	9	50	33	41
(*n*= 34) number	14	3	17	11	14

Training

When asked how participants learned to prepare medications safely by using a filter needle with an ampule in the initial survey, the majority (67%; 29/43) indicated it was "on the job" training while learning to practice anesthesia. Two percent (1/43) learned about filter needle use with ampules from textbooks, 2% (1/43) from laboratory experiences, 16% (7/43) from a combination of all of these areas, and 12% (5/43) from none of the previously mentioned areas (Table 8).

Fifty-nine percent of the participants in the follow-up survey signified that they learned about using a filter needle with an ampule "on the job". Six percent learned about se with ampules from textbooks, 0% from laboratory experiences, 26% from all of these areas, and 9% from none of these areas. This finding is similar to responses on the first survey when 67% participants indicated they were taught about using filter needles with ampules while "on the job" (Table 8). Table 8 indicates the type of training regarding filter needle use with ampules the anesthesia provider received.

Table 8

Type of Filter Needle Training

Survey/ FN Use Training:	Textbooks	Laboratory	OJT	All	None	Mean	Range
1 (*n*= 43) percentage	2	2	67	16	12	20	65
(*n*= 43) number	1	2	29	7	5	9	28
2 (*n*= 34) percentage	6	0	59	26	9	20	53
(*n*=34) number	2	0	20	9	3	7	18

Note. OJT= on-the-job

Practice Change

The majority (81%; 35/43) of the anesthesia provider participants in the first survey said they would change their practice by using a filter needle when preparing medication from ampules if there was an evidence-based practice standard that existed. No participants said they would not change their practice. However, 19% (8/43) demonstrated that "maybe" they would change their practice if an evidence-based practice standard did exist (Table 9).

When asked on the follow-up survey "have you changed your practice" by using a filter needle when preparing medications from ampules, 44% said "yes", 26% said "no", and 29%

”maybe”. Eighty-one percent of the pre-intervention participants said they would change their practice if they knew of an evidence-based standard regarding filter needle use with ampules, but only 44% indicated that they actually did change their practice post intervention (Table 9). This does show an increase in filter needle use as 39% of AP post-intervention said that they already were using filter needles. When this 39% percent is added to the 44% that did change practice, it means that 83% of AP used filter needles when preparing medications from glass ampules post-intervention! Table 9 represents data of “would change” or “did change” practice of the anesthesia provider regarding filter needle use with ampules if a known standard existed.

Table 9

Would/Did Change Practice Known Filter Needle Use Standard

Survey/ Change Practice Known Standard:	Yes	No	Maybe	Mean	Range
1 (*n*= 43) percentage (Would Change)	81	0	19	33	62
(*n*= 43) number	35	0	8	14	27
2 (*n*= 34) percentage (Did Change)	44	26	29	33	18
(*n*= 34) number	15	9	10	11	6

Filter Needle Use Inventory Tracking Results

Filter needle use was tracked by looking at the purchase order history inventory pre and post education intervention via an inventory purchase order tracking software system already in use by the facility. The data were retrieved by a senior supply chain analyst working for the healthcare system where the project was implemented. The original plan was to track filter needle use (purchase order history) three months prior to the project (January, February, and March 2014). A separate tracking of filter needle use during the month of April 2014 was planned while the initial survey was distributed. Then, the final aspect of the filter needle use

tracking plan was to analyze the data for the three months after the initial survey and education intervention (May, June, and July 2014). There were no transaction histories available in the inventory tracking software for filter needle purchase ordering in January, March, or April 2014, so the only month pre-intervention that was documented was February 2014. The data of filter needle use in February 2014 was 115 items (actual filter needle count). The count for May, June, and July 2014 were: 120, 94, and 575, respectively. There were five times more filter needles used during the third month post intervention (July) than the month of February, the only month prior to the intervention with data. Table 10 illustrates filter needle purchase order history by months: pre-intervention count (number of filter needles used), intervention count, and post-intervention count.

Table 10

Filter Needle Purchase Order History Results

Pre-Intervention:			Intervention:	Post-Intervention:		
January	February	March	April	May	June	July
0	115	0	0	120	94	575

Outcome

The findings of this quality improvement project strongly suggest that the overall project objective was achieved. The project objective was to improve anesthesia provider compliance to existing standards after being presented the evidence that strongly suggested the possibility of patient harm from GPC. The finding that there was an overall five-fold increase in the number filter needles purchased/ordered after the education intervention than prior to the intervention (i.e., February= 115/July= 575), indicates that anesthesia providers did use filter needles more often after than before the education intervention. Also, the finding that 83% of AP (39% already

used filter needles and 44% changed their practice to use filter needles) used filter needles post-intervention further validates this point. This increase in filter needle use by anesthesia providers increases patient safety by reducing patient risk of harm from glass particle contamination.

Unintended Consequences

Unintended consequences of a project can have both positive and negative implications. These unanticipated outcomes can have an inadvertent benefit (positive consequence) or an unexpected detriment (negative consequence) to the project outcomes. This section of chapter four presents the unintended consequences of this project determined by the author.

Positive Unintended Consequences Implications

Listed below are some of the implications of the positive consequences noted by the author. They include:

1. The main operating room pharmacist was surprised to learn that many anesthesia providers were not aware of or practicing established standards when preparing medications from glass ampules. A discussion followed regarding the need to re-educate all perioperative staff regarding filter needle use with glass ampules on an annual basis.
2. Increased informal discussion about safe injection practices and filter needle use with ampules was noted among anesthesia providers by the author.
3. Better communication among staff to re-stock the anesthesia cart with filter needles was noted by discussion with the anesthesia technicians that stock the cart daily to ensure ready availability.

Negative Unintended Consequences Implications

Listed below are some of the implications of the negative unintended consequences related to this project. They include:

1. Many anesthesia providers in the participant group practice at multiple healthcare facilities (3 different hospitals, 3 different surgery centers, etc.). This project was conducted at only one facility. Some of the other facilities may have filter needles readily available for anesthesia staff to use when preparing medications from glass ampules. Frustration was expressed by some providers due to lack of filter needle availability. Consistency among facilities is needed in order to have filter needles available for anesthesia providers. This negative consequence can also be considered an unexpected benefit as anesthesia providers are requesting availability of filter needles at all clinical practices sites. This project could easily be implemented at other facilities to improve compliance to standards.
2. Awareness by the author that blunt tip filter needles, recommended by the Infusion Nurses Society, were not available at the site of intervention implementation. Only the sharp hypodermic filter needle was available for use by anesthesia providers. The use of the sharp filter needle increases the risk of occupational needle stick hazard by the provider. Discussion to purchase blunt tip filter needles are ongoing with pharmacy and anesthesia supply specialists to provide blunt tip filter needles at the anesthesia medication preparation site for maximum provider safety.

Summary

Chapter four presented the statistical analysis of the data collected in this project. Included were data collected from the pre-intervention survey, the post-intervention survey, and the filter needle purchase order history information (pre and post-intervention). The main outcome determined from these findings is that the objective of this project was achieved as evidenced by an increase in anesthesia provider compliance of filter needle use with glass ampules following the education intervention. This was validated by the five-fold increase of filter needle use data retrieved from the purchase order history inventory tracking software. The next chapter, chapter five, offers the discussion section of this project.

Chapter Five: Discussion

This chapter will present the interpretation of the results of this project from chapter four. The discussion also includes the significance of the findings, the limitations of this project, future recommendations for continuation of the project, implications for practice, and a conclusion. The discussion begins with the interpretation of results.

Interpretation of Results

The results of this project indicate the following:

1. Most anesthesia providers (81%, 35/43) said they would change their practice prior to the intervention, but only 44% (15/34) reported actually changing their practice after the intervention. This finding is inconsistent with the filter needle inventory data post-intervention noting a five-fold increase in filter needle use. However, 83% of the participants self-reported using filter needles with ampules on the post-intervention survey. This includes 44% that changed their practice and 39% that were already using filter needles with ampules.
2. Anesthesia providers use glass ampules that contain medications regularly in practice. The use of medication ampules warrants the use of filter needles according to established pharmacy and nursing standards. These results are consistent with the findings of Farmer et al. (2012).

3. Anesthesia providers use filter needles with ampules more often after an education intervention as indicated by the five-fold increase (115/575) in filter needle use via the purchase order tracking history three months after the intervention.
4. More anesthesia providers were aware of filter needle availability post intervention; Sixty-five percent (22/34) indicated that filter needles were readily available post-intervention compared to 51% (17/43) pre-intervention.
5. Awareness of facility standards and organizations with standards of filter needle use improved after intervention; Facility standard awareness was 35% (12/34) "yes" after the intervention compared to 14% (6/43) "yes" of participants were aware before intervention. Awareness of organizations with filter needle use standards also improved post-intervention with 41% (14/34) saying they were aware after compared to 28% (12/43) prior to education.

Significance of Results

In this project an education intervention presented the evidence-based research regarding GPC and the risk of patient harm. Participants in this project changed their practice based on this evidence to incorporate safe injection practices when preparing medications from ampules. As a result, existing best practice standards were followed and patient safety improved.

Limitations

The limitations noted while implementing this project follow:

1. Participants may have answered questions more accurately had they not been asked the two demographic questions regarding type of provider and number of years in practice thinking they may have been easily identified by the author.

2. Since most participants travel to a variety of facilities to provide anesthesia services, they may have answered questions with a different facility in mind other than the facility where the project actually took place (tracking of filter needles).
3. Some participants may have answered question nine on the second survey regarding "have you changed your practice by using a filter needle with ampules" by stating "no" because they already were using filter needles before the project intervention. Therefore, they did not change their practice.
4. Fifteen percent (5/34) of the participants of the second survey did not participate in the initial survey. Therefore, they did not receive the education presentation.

Recommendations for Continuation

It is recommended from this project that in-service education on the harm of not using filter needles and the benefit of using filter needles be given to anesthesia providers to increase filter needle use. The perioperative pharmacist needs to include filter needle use with ampules when orienting new staff and provide posters at the medication preparation site for anesthesia providers as well as all other perioperative staff. All perioperative nursing (surgery admission center, pre-operation holding area, intra-operative circulating, and post-anesthesia care unit) staff should include an annual review of correct preparation of medications from glass ampules by using filter needles. Anesthesia and surgical technicians should also have an annual filter needle with ampules review. Finally, all anesthesia providers should participate in an orientation of safe medication preparation and safe injection practices upon hire as part of the new hire orientation process and annually thereafter. This can be done through the already existing annual education competency checklist required by the perioperative staff. This education project should be

implemented in all three hospitals within the healthcare system, not just the one site where this quality improvement project took place.

Implications for Practice

Anesthesia providers have an ethical responsibility to follow established guidelines when preparing medications from glass ampules. Safe injection practices will reduce the amount of glass particle contamination and therefore, the risk of patient harm. Providing an education intervention to anesthesia providers can increase an awareness of the evidence supporting compliance to existing standards regarding filter needle use with ampules.

The review of the evidence revealed that glass particle contamination occurs when opening an ampule (Preston & Hegadoren, 2004; Zabir et al., 2008; and Kalinski et al., 2012), filter needle use reduces this contamination (Kalinski et al., 2012), and glass particle contamination has caused harm to patients (Puntis et al., 1992, Jack et al., 2010). The risk of patient harm, phlebitis for example, from glass particle contamination can be reduced with the use of filters (Niel-Weiss et al., 2010). Anesthesia providers do not routinely use filter needles when preparing medications from ampules, are not aware of existing filter needle use standards or organizations that endorse these standards, and that filter needles may not be readily available on the anesthesia cart which is the site of medication preparation (Farmer et al., 2012).

Anesthesia providers need to be re-educated upon hire and annually by participating in an education intervention regarding the use of filter needles with glass ampules and be provided information on the existing standards (USP, 2008) for filter needle use with ampules as well as made aware of organizations that endorse these standards (ASHP, 2008, INS, 2011). All anesthesia carts need to be stocked with filter needles daily for ready use by providers where

they regularly prepare medications from ampules. Patient safety in medication preparation, administration, and safer injection practices will be improved when glass particle contamination is reduced by anesthesia provider compliance to evidence-based practice standards when preparing medications properly by using a filter needle with ampules (Stein, 2006). The AANA needs to update their position statement and guidelines on *Safe Injection Practices for Needle and Syringe Use* (2014) to include filter needle use with ampules.

Conclusion

The findings from this project suggest that anesthesia provider compliance regarding filter needle use with glass ampules can be improved by participating in an education intervention. This project was shown to be effective based upon the following evidence: there was a five-fold increase in filter needle usage three months post intervention anesthesia providers increased awareness of standards and organizations that endorse standards regarding filter needle use; filter needles were made available for use at the medication preparation site; and anesthesia provider knowledge of reducing glass particle contamination to decrease the potential of patient harm has contributed to the success of this project. Participants in this project indicated an increase awareness of the importance of adherence to safe injection practices toward accomplishing the aim of better patient outcomes by their compliance to these standards.

Appendix A: SVMC IRB Exempt Letter

Institutional Review Board
1 Shircliff Way, Suite 1223
Jacksonville, FL 32204
Office: 904-308-8124
Fax: 904-308-7326

DATE: December 9, 2013

TO: Debran L. Harmon, CRNA, MSN, MAT, MSH, ARNP

FROM: St. Vincent's Medical Center IRB

STUDY TITLE: [534534-1] Anesthesia Safety: Filter Needle Use with Glass Ampules

IRB REFERENCE #: 13-12-03 SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF EXEMPT STATUS

DECISION DATE: December 5, 2013

REVIEW CATEGORY: Exemption category #45 CFR 46.101(b) (2)

Thank you for your submission of New Project materials for this research study. The St. Vincent's Medical Center IRB has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

We will put a copy of this correspondence on file in our office.

If you have any questions, please contact Terri Shad at or . Please include your study title and reference number in all correspondence with this office.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained in the St. Vincent's IRB records.

Appendix B: UNF IRB Exempt Letter

UNF
UNIVERSITY of
NORTH FLORIDA.

Office of Research and Sponsored Programs
1 UNF Drive
Jacksonville, FL 32224-2665
904-620-2455 FAX 904-620-2457
Equal Opportunity/Equal Access/Affirmative Action Institution

MEMORANDUM

DATE: February 17, 2014

TO: Ms. debran Harmon, CRNA, MSN, MAT, MSH, ARNP

VIA: Dr. Patrick Monaghan
Nursing

UNF IRB Number: 548108-1
Approval Date: 02-17-2014
Expiration Date: Exempt - None
Processed on behalf of UNF's IRB KLC

FROM: Dr. Jennifer Wesely, Chairperson
On behalf of the UNF Institutional Review Board

RE: Review of New Project by the UNF Institutional Review Board IRB#548108-1:
"Anesthesia Safety: Filter Needle Use with Glass Ampules"

This is to advise you that your project, "Anesthesia Safety: Filter Needle Use with Glass Ampules" was reviewed on behalf of the UNF Institutional Review Board and has been approved as . Therefore, this project requires no further IRB oversight unless substantive changes are made.

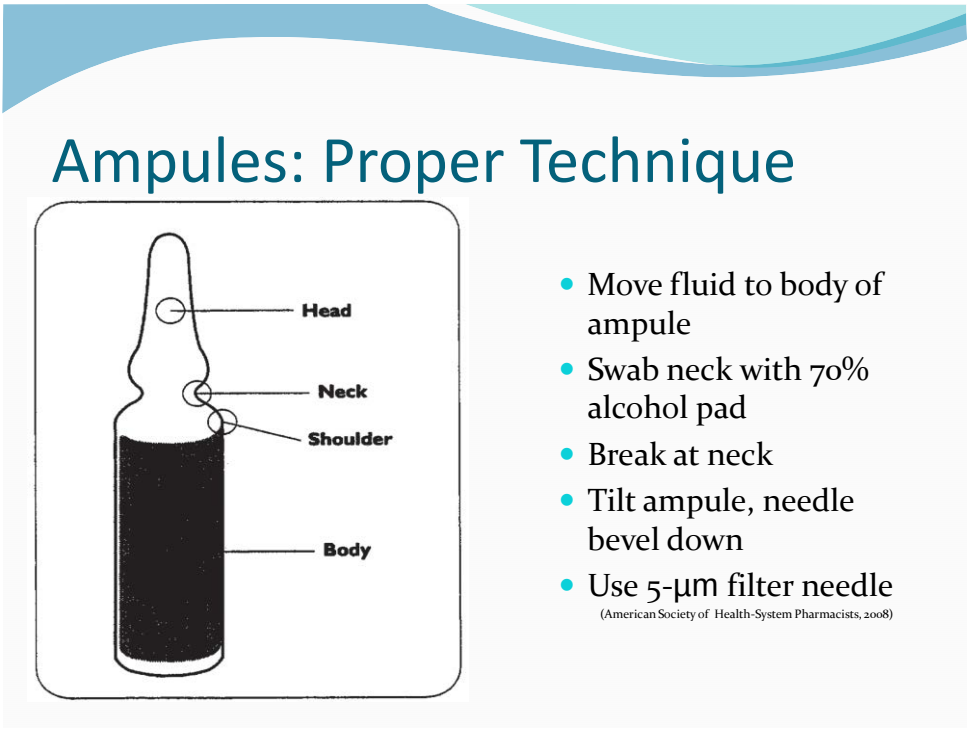
This approval applies to your project in the form and content as submitted to the IRB for review. All participants must receive a stamped and dated copy of the approved informed consent document when possible. Any variations or modifications to the approved protocol and/or informed consent forms that are substantive or might increase risk to human participants must be submitted to the IRB prior to implementing the changes. Please see the for additional information about what types of changes might require an amendment. Any unanticipated problems involving risk and any occurrence of serious harm to subjects and others shall be promptly to the IRB within 3 business days.

Your study has been approved as of 2/17/2014. Because your project was approved as exempt, no further IRB oversight is required for this project unless you intend to make a change that is considered substantive or might elevate risk to participants. As an exempt study, continuing review will be unnecessary. When you are ready to close your project, please complete a which can also be found in the documents library called "Forms and Templates" in IRBNet. This closing report will need to be submitted as a new package in IRBNet.

CITI Course Completion Reports are valid for 3 years. Your completion report is valid through 7/11/2014 and Dr. Monaghan's CITI training is valid through 9/19/2015. **Please note that your CITI certification will expire this year.** Before your certification expires in July, please complete the Refresher Course which is much

Appendix C: Anesthesia Cart Educational Poster

Educational Poster



Posted near Anesthesia Cart and on door of OR Pharmacy

Appendix D: Filter Needle Use Survey

PRE-Education Intervention Survey: <u>Filter Needle Use with Glass Ampules</u>

1. Indicate type of anesthesia provider: (choose one)
   Anesthesiologist____ CRNA____ AA____
2. How many **years** have you been practicing anesthesia as a credentialed provider?
   1-2 3-5 6-10 11-15 16-20 >20
3. Approximately how many glass ampules on **average** do you use **per day** in your anesthesia practice?
   0 1-5 6-10 11-15 16-20 >20
4. How often do you **use** a filter needle/straw when preparing medication from a glass ampule?
   Never Rarely Sometimes Often Always
5. Are filter needles/straws **readily available** at the medication preparation site (anesthesia cart)?
   YES NO Unknown
6. Are you aware of any **established standards** of practice required at your facility regarding the use of filter needles with glass ampules?
   YES NO Unknown
7. Are there any **agency(s) or organization(s)** that have established standards regarding the use of filter needles/straws with glass ampules?
   YES NO Unknown
8. Which of the following types of **training** did you participate in during your anesthesia education regarding the proper techniques when preparing medication from glass ampules? (circle any that apply)
   Textbooks Laboratory On the Job All of these None of these
9. Would you **change your practice** by using a filter needle/straw when preparing medication from an ampule if you knew there were evidence-based practice established standards?
   YES NO Maybe

POST-Education Intervention Survey: (same as above except omit #9 and add the question below)

10. Have you **changed your anesthesia practice** by using a 5-micron filter needle/straw when preparing medications from glass ampules after participating in this project?
    YES NO Maybe

Appendix E: Education Presentation

Anesthesia Safety: Filter Needle Use With Glass Ampules

debran L. Harmon, CRNA, MSN, MAT, MSH, ARNP

Learner Outcomes

- Review existing evidence related to the use of filter needles when preparing medication from a glass ampule.
- Present established Standards of Practice regarding filter needle use with ampules.
- Suggestions for evidence-based best practice to promote patient safety when preparing medications from glass ampules.

Glass Particle Contamination

What We Know

- Glass contamination of medication occurs when opening glass ampules (Zabir, Choy, & Rushdan, 2008; Carbone Trotter & Sheikh, 1991)
- Glass particles may be injected IV, epidural/SA spaces causing potential harm to patients (Fernandez, Cuc, Alcandia & Alhaji, 2011)
- Damage to: veins, lungs, brain, liver, kidney, spleen, intestines
  - Pulmonary thrombi and micro-emboli
  - Vascular phlebitis and pain
  - End-organ tissue granuloma formation and inflammation

(Garvan and Gonner, 1964; Saban, Cheng, Stommel, & Hennen, 1999)

Clinical Effects of Particles

Direct embolization

Glass fragments embedded in lung tissue in post mortem specimens from the lung of neonates

What We Know

- **Most vulnerable patients:** pediatric (premature neonates), geriatric, immunocompromised patients (poly-trauma, ICU patients) (Heiss-Harris & Verklan, 2005)
- Using filter needles can reduce glass particle contamination (Preston & Hegadoren, 2004; Saban, Cheng, Stommel, Hennen, 1989)
- Smaller ampules=less glass contamination
- Smaller gauge needles/filter straws=fewer glass particles (Zabir, Choy, & Rushdan, 2008)

Appendix E: Education Presentation (continued)

9/8/2014

Clinical Question

What is the current usage of filter needles for the administration of medication from glass ampules by anesthesia providers?

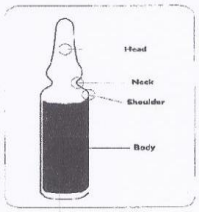
Closer Look at our Practice

- Do we use glass ampules, what drugs, how many per day?
- Do we have filter needles at our place of practice, if so, where are they located? Are they readily available at the MED prep site?
- Do we use filter needles when drawing MED from a glass ampule? (IV, SAB (IT), Epidural injections)
- Is there a written protocol/policy that requires the use of filter needles with glass ampules?

What We Can Change

- Use proper technique when preparing medications from glass ampules
- Have filter needles readily available at the medication preparation site (anesthesia cart) for providers
- Use filter needles each & every time we draw up medication from a glass ampule regardless of route (IV, IT, Epidural)
- Consider developing a protocol/policy for anesthesia providers regarding medication preparation from glass ampules consistent with USP and INS standards & guidelines.

Ampules: Proper Technique



- Move fluid to body of ampule
- Swab neck with 70% alcohol pad
- Break at neck
- Tilt ampule, needle bevel down
- Use 5-µm filter needle

(American Society of Health-System Pharmacists, 2003)

Filter Needle Aspiration

Standards & Guidelines

- **U. S. Pharmacopeia (USP)**
- Chapter <797> for Compounding Sterile Preparations (CSP)
- TJC considers 797 as best practice
- **American Society of Health-System Pharmacists (ASHP)**
- Use a 5-µm filter needle or straw when drawing medication from a glass ampule*
- **Infusion Nurses Society (INS) - Standards of Practice 2011**

Standard 28.6 states:

"A blunted filter needle or filter straw shall be used when drawing medication from glass ampules" (p. 34)

*ASHP Guidelines on Handling Hazardous Drugs (p. 42)

2

Appendix E: Educational Presentation (continued)

Primum non nocere

- First, Do No Harm
- Be an advocate for patient safety
- Err on the side of safety, use filter needles when drawing medications from glass ampules

References

- American Society of Health-System Pharmacists. (2008). Sterile Injectable Compounding. In *ASHP Discussion guide on USP Chapter <797>*. Retrieved from http://www.ashp.org/s_ashp/docs/files/Discussion797_SterileCmpd.pdf
- B. Braun (2011). Particulate Contamination: Risk Prevention in Infusion Therapy. Retrieved from http://safeinfusiontherapy.com/
- Bowser, J. H., & Pavesky, J. H. F. (1942). An in vitro and in vivo study of glass particles in ampules. *Journal of the American Pharmaceutical Association*, *Vol 031*, 289–295.
- Carbone-Tisdale, E. D., & Shanks, C. A. (1990). Glass particle contamination in single-dose ampules. *Anesthesiology Analgesia*, *69*, 1361–1365.
- Carneiro, A. P. (Jr), C. F., de Almeida, C. F., & Allred, R. C. (2011). Glass ampules: Risks and benefits. *Brazilian Journal of Anesthesiology*, *61*(4), 513–516.
- Dawson J.M. & Dunnill B.W. (1964) The harmful effects of particles in intravenous fluids. *Medical Journal of Australia*, *1*, 546.
- Hebe-Harris, G. M. & Sanchez, M. T. (2001). Maximizing patient safety: Filter needle use with glass ampules. *Journal of Perianesthesia Nursing*, *16*(5), 343–351.
- Infusion Nurses Society. (2011). Infusion nursing standards of practice. *Journal of Infusion Nursing*, *34*(1S), S1–S109.
- Pandey, C. S., & Hegadekere, K. (2004). Glass contamination in parenterally administered medication. *Journal of Advanced Nursing*, *48*(3), 264–268.
- Parish, J. W. L., Wilkes, E. M., Bell, P. A., Eveleigh, D. I., & Scott, I. W. (1972). Hazards of parenteral treatment: Do particles count? *Archives of Disease in Childhood*, *47*, 1475–1477.
- Sasaki, G. L., Chang, E. T., Diamond, E. A., & Munson, C. R. (1989). Glass particle contamination: Influence of aspiration methods and ampule types. *ANESTHESIOLOGY*, *71*, 959–961.
- U. S. Pharmacopeia (2008). Chapter <797> Pharmaceutical Compounding: Sterile Preparations.
- Zaidi, A. F., Chen, C. Y., & Ibrahim, E. (2008). Glass particle contamination of parenteral preparations of intravenous drugs in anaesthetic practice. *South African Journal of Anesthesia and Analgesia*, *14*(4), 17–18.

Appendix F: Evidence Matrix Table 1

Studies Investigating Filter Needle Use with Ampules Sorted by Level of Research Design

Author (Date)	**Design**	**Sample**	**Outcome**	**Intervention**	**Results**	**Limitations**
Niel-Weise et al. (2010)	Systematic Review	Meta Analysis of 11 Randomized Controlled Trials (RCT)	No recommendation for routine in-line filter use	Effect of in-line filters on infusion phlebitis via PIVCs	All 11 RCTs showed reduced risk in infusion phlebitis with in-line filter use	Unexplained statistical heterogeneity & methodological shortcomings among trials
Zabir et al. (2008)	RCT (IV)	360 ampules (amp)	Larger amp size higher % Glass Particle Contamination (GPC)	Amp size (mL): 1, 2, 5, 10 Needle Gauge (g): 23, 18, filter straw (FS)	4.2 % GPC, reduced GPC with FS & 23 g compared with 18g needles	Single blinded; GPC counting technique flawed
Preston & Hegadoren (2004)	RCT (IM)	108 amp	Larger bore needles >GPC than smaller bore or Filter Needle (FN)	54-1 mL amp 54-2 mL amp 18-18g, 18-21g, 18- 19g Filter Needle	22% 1 mL GPC (18g); 56% 2 mL GPC (18g) 39% 2 mL GPC (21g); 0% GPC 19G FN	Speed of aspiration not controlled; amp from one manufacturer
Hemingway et al. (2007)	Case Control (neuroaxial)	Part I: 100 amp Part II: 100 amp	Part I: 18% grew organisms (GO) Part II: most contamination in NA amps	Part I: 50 alcohol (A); 50 no alcohol (NA) Part II: 4 groups (25 each); NA/no FN; NA/FN; A/no FN; A/FN	Part I: 18% NA GO; 0% A Part II: NA > contamination; FS< contamination & GPC	Examined 5 micron FN, not 0.22 micron epidural filters; gloves/hand washing not required
Heiss-Harris & Verklan	Case Study (neonates)	25 NICU RNs surveyed-knowledge and	NICU RNs were not using FN with Infant	FN use education; FN use written	24% used FN with amp before intervention; 90%	Informal observation/evaluation; long term compliance

(2005)		use of FN with amp	MED via Central Line	protocol	compliance after intervention	rate not measured
Stein (2008)	EBP	Best practice article	Competency checklist for withdrawing medication from ampule	Annual competency validation medication preparation using FN with amp	Adding the "right" technique" in medication preparation as the 6th "R"	Strategies for FN use with amp compliance not measured
Farmer et al. (2012)	Cohort (survey)	124 anesthesia providers (80 CRNAs; 44 SRNAs)	69% rarely use FN-not available; 90% often use FN-readily available (RA); 100% always use FN-RA	none	85% use amp daily/weekly; 60% rarely/never use FN; 86% no policy FN use	Non-piloted survey tool
Kalinski et al. (2012)	Bench Study (20 trials)	10-2 mL amp, 18g non-FN (NFN) 10-2 mL amp, 19g FN	NFN 1286 GP; 3 microns base diameter (BD) FN 182 GP; 4.3 microns BD	FlowCAM-particle analyzer/flow cytometer to count & measure GP	Fewer glass particles in sample when FN used, FN does not eliminate the presence of GP	One type of amp used

IV-intravenous, PIVCs- peripheral intravenous catheters, IM-intramuscular; RCT-random controlled trials, EBP-evidence-based practice; NICU-neonatal intensive care unit; RN-registered nurse; CRNA- certified registered nurse anesthetist, SRNA-student registered nurse anesthetist; MED-medication.

Appendix F: Evidence Matrix Table 2

Additional Studies Investigating Glass Particle Contamination/Filter Needle Use with Ampules Sorted by Level of Research Design

Author (Date)	**Design**	**Sample**	**Outcome**	**Intervention**	**Results**	**Limitations**
Carbone-Traber & Shanks (1986)	RCT: randomized, blinded, controlled	Phase I : *n= 30* amps Phase II: *n= 40* amps	Smaller amps, less GPC; no difference in GPC with aspiration technique	amp size (mL): 1, 5, 10 aspiration Technique: 3mm tubing, 18g, 25g, 19g FN	GPC< 1<5 <10 mL amps; GPC occurs even with 25g or FN during aspiration	Filtered microscopic technique used
Garvan & Gunner (1964)	RCT	Animals (rabbits) & Humans	GPC: pulmonary granuloma formation & inflammatory reactions	Rabbits & humans received IV fluids	Rabbits: 500 mL IVF 5000 granulomas in lungs; Humans: 40-50 L IVF/pulmonary fibrosis & vascular granulomas	Findings dependent upon microscopist
Brewer & Dunning (1947)	RCT: several experiments	Animals: rabbit ear veins & mice veins *n >1000*	GPC in lungs, liver, spleen, intestines, & kidneys; pulmonary vascular obstruction	GPC solutions injected over time in animals; attempt to create fatal emboli	GPC 32 days: 1.3 %; GPC 1 year: 2%; massive doses of GPC cause pathology; no fatal events	Visual & microscopic inspection of particles
Puntis et al. (1992)	CT: post mortem	Infants: TPN *n= 41*; SIDS *n= 32* (control)	GPC neonates lungs TPN; No GPC in SIDS	necropsy & particle study; automated particle & optical microscope counting	TPN: 5% pulmonary HTN & vascular granulomata	Not double blinded
Sabon et al.(1989)	CT	ampules: *n= 40;* technique*: n= 40*	Using a FN reduces GPC	Part I: aspiration technique	Transparent/metal etched amps > GPC	Dependent upon ability of

			significantly; GPC > clear/metal etched amps	Part II: ampule size	than amber/chemically etched amps	microscopist
Jack et al. (2010)	Cohort	Pediatrics: filters *n=20;*patients *n= 9;* controls *n= 5*	GPC occurs even with filtration & suppresses immune system	in vitro: cytokine levels assayed in endothelial cells & macrophages	Suppression of immune system: fewer macrophages & less endothelial cell cytokine secretion	Simulated in vivo situation

RCT= randomized controlled trials; CT= controlled trials; Amps= ampules; GPC= glass particle contamination; mL= milliliter; g= gauge; FN= filter needle; TPN= total parenteral nutrition; SIDS= sudden infant death syndrome; IV= intravenous; IVF= intravenous fluid

References

American Association of Nurse Anesthetists (2010). Responsibility to the patients (1.2). Code *of ethics for the Certified Registered Nurse Anesthetist.* Retrieved from http://www.aana.com/resources2/professionalpractice/Documents/PPM%20Code%20of%20Ethics.pdf

American Association of Nurse Anesthetists (2012). Position Statement 2.13. *Safe practices for needle and syringe use.* Retrieved from http://www.aana.com/myaana/Publications/membernews/Pages/022309-Alert-Important-New-Position-Statement-on-Safe-Injection-Practices.aspx

American Association of Nurse Anesthetists (2014). *Safe injection guidelines for needle and syringe use*. Retrieved from http://www.aana.com/resources2/professionalpractice/Pages/Safe-Injection-Guidelines-for-Needle-and-Syringe-Use.aspx

American Society of Hospital-System Pharmacists. (2008). Practice basics: Chapter 16. *ASHP Discussion guide on USP Chapter< 797>*. Retrieved from http://www.ashp.org/s_ashp/docs/files/discguide797-2008.pdf

Brewer, J. H. & Dunning, J. H. F. (1947). An in vitro and in vivo study of glass particles in ampules. *Journal of American Pharmacists Association*. 36, pp.289-293.

Brown, L. (2010). Continuous imaging fluid particle analysis: A Primer. Retrieved from http://www.fluidimaging.com/products-particle-imaging-analyzer.htm?gclid=CNvsiPuLy7YCFQgHnQod0DQA7g

Carbone-Traber, K. B., & Shanks, C. A. (1986). Glass particle contamination in single-dose ampules. *Anesthesia and Analgesia*, 65, 1361-1363.

Farmer, H. L., Harmon, d. L., Monaghan, W. P., & Pabalate, J. L. (2012). *Use of Glass Ampules and Filter needles by Anesthesia Providers.* Poster presented at the 79th Annual Meeting of the American Association of Nurse Anesthetists in San Francisco, California.

Garvan J.M. & Gunner B.W. (1964). The harmful effects of particles in intravenous fluids. *Medical Journal of Australia*, 2, 1-6.

Glasziou, P., Del Mar, C., & Salisbury, J. (2007). *Evidence-based practice workbook* (2nd ed). Malden, MA: Blackwell Publishing.

Heiss-Harris, G. M. & Verklan, M. T. (2005). Maximizing patient safety: Filter needle use with glass ampules. *Journal of Perinatal & neonatal Nursing.* 19(1), 74-81.

Hemingway, C.J., Malhotra, S., Almeida, M., Azadian, B., & Yentis, S. M. (2007). The effect of alcohol swabs and filter straws on reducing contamination used for neuroaxial injections. *Anaesthesia*. 62(3), 286-288.

Infusion Nurses Society. (2011). Infusion nursing standards of practice. *Journal of Infusion Nursing*, 34(1S), S1-S109.

Jack, T., Brent, B. E., Boehne, M., Mueller, M., Sewald, K., Braun, A., Wessel, A., & Sass, M. (2010). Analysis of particulate contaminations of infusion solutions in a pediatric intensive care unit. *Intensive Care Medicine, 36, 707-711.*

Kalinski, D. A., Waters, A. I., Monaghan, W. P., Pyati, R., Harmon, d. L., & Pabalate, J. L. (2012). *A Comparison between Filter needles vs. Non-Filter needles on Glass Particle Contamination of the Aspiration from Glass Ampules.* Poster presented at the 79th Annual Meeting of the American Association of Nurse Anesthetists, California.

Kastango, E. S. (2007). A review of Chapter 797 and 788: New regulations and their impact on pharmacists [Monograph]. *Literature Review,* New York: McMahon Publishing Group.

Melnyk, B. M. & Fineout-Overholt, E. (2011). *Evidence-based practice in nursing & healthcare: A guide to best practice* (2nd ed.). Philadelphia, PA: Wolters Kluwer Health.

Niel-Weise, B., Stijnen, T., & van den Broek, P. (2010). Should in-line filters be used in peripheral intravenous catheters to prevent infusion-related phlebitis? A systematic review of randomized controlled trials. *Anesthesia & Analgesia*, 110(6), 1624-1629. doi: 10.1213/ANE.0b013e3181da8342

Preston, S. T., & Hegadoren, K. (2004). Glass contamination in parenterally administered medication. *Journal of Advanced Nursing*, 48(3), 266-270.

Puntis, J.W.L., Wilkins, K.M., Ball, P.A., Rushton, D.I., & Booth, I.W. (1992). Hazards of parenteral treatment: Do particles count? *Archives of Disease in Childhood,* 67:1475-1477.

Qualtrics (2014). Online survey tool. Version 58147, Provo, UT.

Sabon, R. L., Cheng, E. Y., Stommel, K.A., & Hennen, C. R. (1989). Glass particle contamination: Influence of aspiration methods and ampule types. *Anesthesiology*, 70, 859-862.

Shaw, N.J. & Lyall, E. G. H. (1985). Hazards of glass ampules. *British Medical Journal,* 291, 1390.

Stein, H. G. (2006). Glass ampules and filter needles: An example of implementing the sixth 'r' in medication administration. *Medsurg Nursing.* 15(5), 290-4.

United States Pharmacopeia (2008). Chapter 797 Pharmaceutical Compounding: Sterile Preparations. Retrieved from http://www.pbm.va.gov/LinksAndOtherResources/USP%20797%20Pharmaceutical%20Compounding%20-%20Sterile%20Compounding.pdf

Zabir, A. F., Choy, C. Y., & Rushdan, R. (2008). Glass particle contamination of parenteral preparations of intravenous medications in anaesthetic practice. *South African Journal of Anesthesia and Analgesia*, 14(3), 17-19.

VITA

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